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10/681,745	10/08/2003	Suzie Hwang Pun	ITI-P01-010	8153

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	**PAPER NUMBER**
1627	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	**Application No.** 10/681,745	**Applicant(s)** PUN ET AL.
	Examiner TIMOTHY E. BETTON	**Art Unit** 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5-17 and 18-36* is/are pending in the application.

4a) Of the above claim(s) *6,8 and 18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7,9-17 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants remarks filed on 8 October 2009 has been acknowledged and duly made of record.

Status of the Claims

Claims 1-2, 4-5, 7, 9-17, and 31-36 are pending further prosecution on the merits. Claim 3 is cancelled. Claims 6, 8, and 18-30 are withdrawn from further consideration.

Response to Arguments

Essentially, applicants argue that c*laim rejections under 35 USC § 112* be withdrawn in view of the amendments to claims 31 and 32 respectively.

Applicants' amendment is considered and the c*laim rejections under 35 USC § 112* are withdrawn.

Applicants' Further argue that claims 1-5, 7, 9-17 and 31-36 which were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kosak (U.S. Patent No. 6,048,736) in view of Yoshimoto et al. (U.S. Patent No. 5,376,509), Traitler et al. (U.S. Patent No. 4,776,984) and Amiel et al. ("New Associating Polymer Systems Involving Water Soluble beta-Cyclodextrin polymers" Journal of Inclusion Phenomena and Molecular Recognition in Chemistry 25:61-67, 1996) are irrelevant and improper in view of the amendment of the current claims.

Essentially, applicants argue that Kosak does not teach alone or in combination, a polymer composition having a plurality of inclusion hosts; linking molecules, each linking molecule comprising at least two moieties that form inclusion complexes with the inclusion hosts; and at least one biologically active compound or prodrug form thereof, where the linking molecules crosslink the polymer through inclusion complexes.

Applicants' arguments are considered but are not found persuasive because Kosak et al. encompasses the limitation as disclosed in the current invention drawn to the crosslinking of polymers via inclusion complex formation.

Applicants' argue that Amiel et al. does not teach or suggest a polymer comprising linking molecules, where the linking molecules include at least two moieties that form inclusion complexes with the inclusion hosts, where the linking molecules crosslink the polymer through inclusion complexes, and where the polymer also comprises a biologically active compound or prodrug thereof.

Applicants' arguments are considered but are not found persuasive because Amiel et al. was not employed to teach at least two moieties that form inclusion complexes with the inclusion hosts, where the linking molecules crosslink the polymer through inclusion complexes, and where the polymer also comprises a biologically active compound or prodrug thereof. Amiel et al. was employed to overcome the limitations of claims 31 and 32 which are drawn to intramolecularly and intermolecularly.

Applicants' argue that Yoshimoto et al. and Traitler et al. do not teach or suggest a polymer with linking molecules that can crosslink a polymer through inclusion complexes.

Applicants' arguments are considered but are not found persuasive because Yoshimoto was employed to show the direct relationship between a cyclodextrin component and linking molecules.

Further, Kosak et al. is further obvious over the amendment to claims 1, 15, and 16 which are drawn to *at least one biologically active compound or prodrug thereof* in that Kosak et al. clearly teach on page 6 at the first two lines of the 2nd paragraph cyclodextrin polymers for carrying drugs and other active agents. Thus, it would be instantly apparent to the one of skill that the amendment as disclosed in the current claim set drawn to a biologically active compound or prodrug would be readily overcome by the express teachings of Kosak et al. *supra.*

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

For the reasons already made of record, the 103(a) rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 7, 9-17, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosak (USPN 6,048,736) in view of Yoshimoto et al. (USPN 5,376,509), Traitler et al. (USPN 4,776,984) and Amiel et al. (New Associating Polymer Systems Involving Water Soluble β-Cyclodextrin Polymers (Journal of Inclusion Phenomena and Molecular Recognition in Chemistry 25: 61-67, 1996.

The current invention provides a material formed by crosslinking a polymer bearing inclusion hosts (such as cyclodextrin) with a linking molecule bearing at least two functional groups that, as inclusion guests, form inclusion complexes with the inclusion host. For polymers in which cyclodextrin is the inclusion host, exemplary inclusion guests include naphthol, adamantane, cholesterol, and derivatives thereof. In certain embodiments, the polymer bears inclusion guests, and linking molecules bearing inclusion hosts such as cyclodextrin are used to crosslink the polymer. Materials according to the above description can be used to deliver therapeutic agents, such as proteins, nucleic acids, and pharmaceuticals.

Kosak teaches methods for preparing compositions of cyclodextrin polymers for carrying drugs and other active agents. Methods are also disclosed for preparing cyclodextrin polymer carriers that release drugs under controlled conditions. The invention also discloses methods for preparing compositions of cyclodextrin polymer carriers that are coupled to biorecognition molecules for targeting the delivery of drugs to their site of action (abstract only).

Kosak discloses within the summary of the invention [that] [i]t has been discovered that the water soluble (or colloidal) cyclodextrin polymer carriers of the instant invention overcome the problems with individual cyclodextrins in the prior art. The instant invention provides new properties and unexpected advantages. In its simplest form, a cyclodextrin polymer carrier comprises a cyclodextrin polymer that has a drug or other active agent **completely entrapped within** (col. 2, lines 29-35).

Kosak teaches embodiments comprising the use of biologically active compounds (drugs) which reasonably includes prodrugs. Specifically Kosak teaches a plethora of active agents that may be incorporated into the polymeric delivery system (please see col. 3, lines 1-67; col. 4, lines 1-16).

Drugs and other active agents delivered as macromolecules through polymer carriers have gained acceptance as a way for improving cancer chemotherapy and other drug therapies.

Also, the prior art now employs drug-antibody or drug-polypeptide conjugates to re-direct anti-cancer and other agents to selected target cells (col. 1, lines 31-37).

Kosak further teaches a polymer composition and the intended use for the transfection of a cell via the following embodiment:

> Active agents include any drugs including anticancer drugs antineoplastic drugs, antifungal drugs, antibacterial drugs, antiviral drugs cardiac drugs neurological drugs, and drugs of abuse; alkaloids (i.e. camptothecins), antibiotics, bioactive peptides, steroids, steroid hormones, polypeptide hormones, interferons, interleukins, narcotics, nucleic acids including antisense oligonucleotides, pesticides, and prostaglandins(col. 3, lines 19-26).
>
> Other specific active agents are anti-viral drugs, nucleic acids and other anti-viral substances including those against any DNA and RNA viruses, AIDS, HIV and hepatitis viruses, adenoviruses, alphaviruses, arenaviruses, coronaviruses, flaviviruses, herpesviruses, myxoviruses, oncornaviruses, papovaviruses, paramyxoviruses, parvoviruses, picornaviruses, poxviruses, reoviruses, rhabdoviruses, rhinoviruses, togaviruses and viriods; any anti-bacterial drugs, nucleic acids and other anti-bacterial substances including those against gram-negative and gram-positive bacteria, acinetobacter, achromobacter, bacteroides, clostridium, chlamydia, enterobacteria, haemophilus, lactobacillus, neisseria, staphyloccus, and streptoccocus; any anti-fungal drug, nucleic acids and other anti-fungal substances including those against aspergillus, candida, coccidiodes, mycoses, phycomycetes, and yeasts; any drugs, nucleic acids and other substances against mycoplasma and rickettsia; any anti-protozoan drugs, nucleic acids and other substances; any anti-parasitic drug, nucleic acids and other substances; any drug, nucleic acids and other substances against heart diseases, tumors, and virus infected cells, among others (col. 3, lines 62-67 bridging col. 4, lines 1-16).

Kosak further teaches the variable types and descriptions of linkage (col. 4, lines 19-54).

Further Kosak teaches the process and describes the process by which a guest molecule such as a active agent molecule is crosslinked. (Please see the paragraph entitled *Captured Guest Cyclodextrin Polymer Carrier*, col. 7, lines 66-7 bridging col. 8, lines 1-38).

The functional attributes of cyclodextrin inclusion is fully made obvious even in the modifications and/or variations of said cyclodextrin inclusion of molecules. The properties of cyclodextrin complexes are art-known and are expected to achieve and manifest certain characteristics that are functionally nonpatentable because of the physical nature of such cyclodextrin complexes.

Kosak further teaches variable forms of linkage which reasonably make the limitations of claims 7, 9-17, and 31-36 obvious in view of claimed invention.

Kosak teaches biocleavable linkages are defined as types of specific chemical moieties or groups used within the chemical substances that covalently couple and cross-link the cyclodextrin polymer carriers. They are contained in certain embodiments of the instant invention that provide the function of controlled release of an entrapped drug or other active agent. Biocleavable linkages or bonds are defined here under two distinct categories or types.

The Cyclodextrin Polymer Carrier essentially teaches the polymer of cross-linked cyclodextrin derivatives that has the distinguishing property of having incorporated a drug or other active agent as a capture guest. The agent has also formed a noncovalent inclusion complex or inclusion compound with the cyclodextrin of the polymer (col. 7, lines 53-64).

The Captured Guest Cyclodextrin Polymer Carrier explanation teaches embodiments drawn to a guest molecule covalently tethered through a spacer to the water soluble CD polymer (please see the last two lines of col. 7 and the first 46 lines of col. 8).

In one embodiment the captured guest molecule is covalently tethered through a spacer to the water soluble (or colloidal) CD polymer to allow formation of a noncovalent complex between the guest and the host CD within the polymer. Cyclodextrin molecules have their functional groups only on the periphery so that the interior is nonreactive. Therefore, in this embodiment, the guest molecule can form a noncovalent inclusion complex within the cyclodextrin polymer host even though the captured guest is covalently tethered to the host periphery.

In another preferred embodiment the capturing is accomplished through complete physical entrapment by the water soluble (or colloidal) CD polymer carrier. In this embodiment, "completely entrapped" means that a captured guest is not covalently coupled to the polymer but is entrapped within the covalently cross-linked polymer of cyclodextrin molecules so that it cannot leave the polymer by diffusion or extraction. Completely entrapped guests cannot escape until the polymer itself has been degraded or the covalent cross-link bonds are cleaved. In this embodiment, essentially all possible exit routes for the guest to leave the polymer have been closed by cross-linking. Therefore, additional guest molecules (of that size or larger), cannot enter the closed polymer to be added to the cyclodextrin polymer carrier.

This is made possible through the unique method for synthesizing the cyclodextrin polymer carriers of the instant invention. The distinguishing principal of the method is that the guest molecules are completely entrapped during polymerization or during the final cross-linking step of making the polymer carrier. Initially, guest molecules are mixed with the "open" components of the cyclodextrin polymer, which may comprise individual cyclodextrins (or derivatives), cyclodextrin dimers, trimers or an open cyclodextrin polymer. An open cyclodextrin polymer means that the polymer is only partially cross-linked so that guest molecules can enter the polymer by diffusion and form complexes with member cyclodextrins. In the final synthesis step of the polymer carrier, the polymer is closed by additional cross-linking which completely entraps the guests.

Kosak further teaches targeted cyclodextrin polymer carriers, biocleavable cross-linking agents, coupling, functional groups crosslinking or coupling agent and intermediate coupling substances which are fully disclosed throughout columns 8-12. The disclosure addresses each and every possible linkage involving cyclodextrin.

Specifically, the adjuvant limitation of claims 13 and 14 would reasonably be encompassed by the teachings of Kosak drawn to an intermediate coupling substance which exemplifies the same exact characteristics as disclosed in claims 13 and 14.

Kosak et al teach intramolecular and intermolecular interactions via the teachings drawn to coupling.

For the instant invention, two distinct types of coupling are defined. One type of coupling can be through noncovalent, "attractive" binding as with a guest molecule and cyclodextrin, antigen and antibody or biotin and avidin. Noncovalent coupling is binding between substances through ionic or hydrogen bonding or van der waals forces, and/or their hydrophobic or hydrophilic properties (col. 9, lines 37-42).

Kosak teaches the incorporation of particles (col. 12, line 24).

Kosak teaches targeted cyclodextrin polymer carriers (col. 8. line 48) which are reasonably distinct molecules according to the limitation of claim 33.

Kosak teaches exclusive inclusion complexation of claim 34 via the teachings directed to captured guest cyclodextrin polymer carriers (col. 7, lines 66 and 67 bridging to col. 8, lines 1-38).

Kosak teaches the limitation wherein the cyclodextrin moieties are appended to the polymer chain (please see col. 7, lines 53-63).

Kosak does not teach each and every embodiment directed to polymolecular associations.

Specifically, Kosak does not adequately teach the limitation drawn to non-covalent, inclusion complexes in association with linking molecules (other than cyclodextrin) which crosslink the polymer via inclusion complexes.

However, Yoshimoto et al. teach [that]the branched cyclodextrin used in the present invention refers to a compound comprised of a known cyclodextrin to which a water-soluble substance such as a monosaccharide or disaccharide as exemplified by glucose, maltose, cellobiose, lactose, sucrose, galactose or glucosammine has been branchingly added or linked, and may preferably include maltosylcyclodextrin comprised of cyclodextrin to which maltose has been linked (the number of linking molecules of maltose may be 1, 2 or 3, whichever is available), and glucosylcyclodextrin, comprised of cyclodextrin to which glucose has been linked (the number of linking molecules of glucose may be 1, 2 or 3, whichever is available (col. 5, lines 45-57).

However, Traitler et al. addresses the limitations drawn to linking molecules crosslinking the polymer through inclusion complexes by teaching several embodiments thus:

The process according to the present invention is characterized in that the mixture is treated with urea dissolved in a lower alkanol in a ratio by weight of fatty acids other than the .DELTA.6 polyunsaturates to urea of from 1:2.0 to 1:4.5, in that the ***insoluble inclusion complex*** formed is separated and in that a fraction enriched with .DELTA.6 polyunsaturated fatty acids, particularly with .gamma.-linolenic acid, is collected in the liquid phase 9col. 1, lines 65-68 bridging col. 2, lines 1-4).

Further, Traitler et al. teach [f]or certain applications, particularly pharmaceutical applications, it is desirable to enrich the mixture of fatty acids emanating from these oils selectively with .DELTA.6 polyunsaturated acids, particularly with .gamma.-linolenic acid. Now, the conventional method of fractionating fatty acids by high-performance liquid chromatography (HPLC) does not enable .gamma.-linolenic acid to be separated from .alpha.-linolenic acid (coll. 1, lines 46 and 47).

Traitler does not teach reasoning as to why there would be motivation to incorporate variable formulations of inclusion complexes in view of the current invention.

However, Amiel et al. resolves the deficiency in Traitler et al. by teaching inclusion complex formation, complexation constants and viscosimetry which measures the onset of such polymolecular associations.

Amiel et al. more directly teaches the reasoning behind the limitation of claims 32 and 33 by teaching variable forms of polymolecular associations.

Specifically, Amiel et al. teach associating polymers have recently become the subject of extensive research with the use of hydrophobically modified polymers [1]. These amphipathic macromolecules are generally obtained from water soluble polymers modified with relatively low amounts of hydrophobic comonomer (1-5 mol %). They exhibit unusual aqueous solution behavior with the appearance of thickening properties above certain polymer concentrations, due to polymolecular associations. The hydrophobic interactions that occur in order to minimize water hydrophobe contacts are at the origin of the polymolecular associations. In this work, a new class of associating polymer systems is proposed. The principle is to add a water soluble f~-cyclodextrin polymer to an aqueous solution of amphiphilic polymer (see 2nd paragraph, page 61).

Thus, it would have *prima facie* obvious to the one of skill at the time of invention to recognize a reasonable expectation of success via the incorporating and combining together of the Kosak and Amiel et al. references.

Kosak essentially teach the invention. The scope and contents of the Kosak reference teach each and every element of the claimed invention as disclosed above. The differences between the prior art and the claims at issue are to specific terms in the instant claims such as *adjuvants, intermolecular and intramolecular, appended, delivery system*, etc. that are disclosed throughout the instant claims. Kosak does not teach these specific terms. However, the properties of cyclodextrin are art-known. Thus, the terminology disclosed in the instant claims drawn to the description of cyclodextrin activity is readily identifiable within the Kosak reference. Kosak also does not expressly teach inter-, intra -, molecular functions but Amiel et al. clearly teach embodiments drawn to polymolecular associations which would reasonably encompass the limitations of claims 31 and 32.

The objective evidence present in the application indicating obviousness is the art-known teachings directed to cyclodextrins and their characteristics, properties, and susceptibilities. Kosak teaches embodiments directed to the *entrapping* quality of cyclodextrin for an active agent. As Kosak has disclosed, cyclodextrin is constructed in such a way as to induce entrapment of the molecule. The variable limitations attributed to cyclodextrin in the instant claims are made obvious via the detailed teachings of Kosak.

Further, Yoshimoto et al. provides reasoning to combine based upon the well-known properties, characteristics, and susceptibilities of cyclodextrin via the forming of linking molecules. Yoshimoto et al. also supports and suggests reasoning to optimize on such linking molecules by teaching at least one linking molecule.

Thus, in view of the teachings and modifications of Yoshimoto et al., it would have been apparent to the one of skill that the cyclodextrin as described would also reflect the same properties in view of the current invention.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

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